

AMENDED IN SENATE JUNE 3, 2015

SENATE BILL

No. 423

Introduced by Senator Bates

February 25, 2015

An act to amend Section 117690 of the Health and Safety Code, relating to medical ~~waste~~, *waste, and declaring the urgency thereof, to take effect immediately.*

LEGISLATIVE COUNSEL'S DIGEST

SB 423, as amended, Bates. Pharmaceutical waste: over-the-counter drugs and nutritional supplements.

~~The existing~~

Existing law, the Medical Waste Management Act, administered by the State Department of Public Health, regulates the management, handling, and disposal of medical waste, as defined, including pharmaceutical waste. For purposes of that act, "pharmaceutical waste" is defined as a prescription or over-the counter human or veterinary drug, as specified, that is waste, as defined, but excludes from that definition certain pharmaceuticals being sent out of state to a reverse distributor, or being sent by a reverse distributor offsite for treatment and disposal, as prescribed.

This bill would additionally exclude from the definition of "pharmaceutical waste," for purposes of regulation under the act, any over-the-counter human or veterinary drug or dietary supplement that is, among other things, characterized and managed as a hazardous or solid waste and, with respect to an over-the-counter human or veterinary drug, is not disposed of on land within the state.

This bill would declare that it is to take effect immediately as an urgency statute.

Vote: ~~majority~~^{2/3}. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 117690 of the Health and Safety Code
2 is amended to read:
3 117690. (a) “Medical waste” means any biohazardous,
4 pathology, pharmaceutical, or trace chemotherapy waste not
5 regulated by the federal Resource Conservation and Recovery Act
6 of 1976 (Public Law 94-580), as amended; sharps and trace
7 chemotherapy wastes generated in a health care setting in the
8 diagnosis, treatment, immunization, or care of humans or animals;
9 waste generated in autopsy or necropsy; waste generated during
10 preparation of a body for final disposition such as cremation or
11 interment; waste generated in research pertaining to the production
12 or testing of microbiologicals; waste generated in research using
13 human or animal pathogens; sharps and laboratory waste that poses
14 a potential risk of infection to humans generated in the inoculation
15 of animals in commercial farming operations; waste generated
16 from the consolidation of home-generated sharps; and waste
17 generated in the cleanup of trauma scenes. Biohazardous,
18 pathology, pharmaceutical, sharps, and trace chemotherapy wastes
19 that meet the conditions of this section are not subject to any of
20 the hazardous waste requirements found in Chapter 6.5
21 (commencing with Section 25100) of Division 20.
22 (b) For purposes of this part the following definitions apply:
23 (1) “Biohazardous waste” includes all of the following:
24 (A) (i) Regulated medical waste, clinical waste, or biomedical
25 waste that is a waste or reusable material derived from the medical
26 treatment of a human or from an animal that is suspected by the
27 attending veterinarian of being infected with a pathogen that is
28 also infectious to humans, which includes diagnosis and
29 immunization; or from biomedical research, which includes the
30 production and testing of biological products.
31 (ii) Regulated medical waste or clinical waste or biomedical
32 waste suspected of containing a highly communicable disease.
33 (B) Laboratory waste such as human specimen cultures or
34 animal specimen cultures that are infected with pathogens that are
35 also infectious to humans; cultures and stocks of infectious agents

1 from research; wastes from the production of bacteria, viruses,
2 spores, discarded live and attenuated vaccines used in human health
3 care or research, discarded animal vaccines, including Brucellosis
4 and Contagious Ecthyma, as defined by the department; culture
5 dishes, devices used to transfer, inoculate, and mix cultures; and
6 wastes identified by Section 173.134 of Title 49 of the Code of
7 Federal Regulations as Category B “once wasted” for laboratory
8 wastes.

9 (C) Waste that, at the point of transport from the generator’s
10 site or at the point of disposal contains recognizable fluid human
11 blood, fluid human blood products, containers, or equipment
12 containing human blood that is fluid, or blood from animals
13 suspected by the attending veterinarian of being contaminated with
14 infectious agents known to be contagious to humans.

15 (D) Waste containing discarded materials contaminated with
16 excretion, exudate, or secretions from humans or animals that are
17 required to be isolated by the infection control staff, the attending
18 physician and surgeon, the attending veterinarian, or the local
19 health officer, to protect others from highly communicable diseases
20 or diseases of animals that are communicable to humans.

21 (2) Pathology waste includes both of the following:

22 (A) Human body parts, with the exception of teeth, removed at
23 surgery and surgery specimens or tissues removed at surgery or
24 autopsy that are suspected by the health care professional of being
25 contaminated with infectious agents known to be contagious to
26 humans or having been fixed in formaldehyde or another fixative.

27 (B) Animal parts, tissues, fluids, or carcasses suspected by the
28 attending veterinarian of being contaminated with infectious agents
29 known to be contagious to humans.

30 (3) “Pharmaceutical waste” means a pharmaceutical, as defined
31 in Section 117747, including trace chemotherapy waste, that is a
32 waste, as defined in Section 25124. For purposes of this part,
33 “pharmaceutical waste” does not include a pharmaceutical that
34 meets any of the following criteria:

35 (A) The pharmaceutical is being sent out of the state to a reverse
36 distributor, as defined in Section 4040.5 of the Business and
37 Professions Code, that is licensed as a wholesaler of dangerous
38 drugs by the California State Board of Pharmacy pursuant to
39 Section 4161 of the Business and Professions Code.

(B) The pharmaceutical is being sent by a reverse distributor, as defined in Section 4040.5 of the Business and Professions Code, offsite for treatment and disposal in accordance with applicable laws, or to a reverse distributor that is licensed as a wholesaler of dangerous drugs by the California State Board of Pharmacy pursuant to Section 4160 of the Business and Professions Code and as a permitted transfer station if the reverse distributor is located within the state.

(C) The pharmaceutical is an over-the-counter human or veterinary drug or dietary supplement that meets all of the following requirements:

(i) Is offered for sale without a prescription.

(ii) Is labeled with information entitled “Drug Facts” or “Supplement Facts,” in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, as amended, (21 U.S.C.A. Sec. 321 et seq.).

(iii) Is characterized and managed as either a hazardous waste pursuant to Chapter 6.5 (commencing with Section 25100) of Division 20, or a solid waste pursuant to Division 30 (commencing with Section 40000) of the Public Resources Code.

(iv) With respect to an over-the-counter human or veterinary drug, is not disposed of on land within the state.

(4) “Sharps waste” means a device that has acute rigid corners, edges, or protuberances capable of cutting or piercing, including, but not limited to, hypodermic needles, hypodermic needles with syringes, blades, needles with attached tubing, acupuncture needles, root canal files, broken glass items used in health care such as Pasteur pipettes and blood vials contaminated with biohazardous waste, and any item capable of cutting or piercing from trauma scene waste.

(5) “Trace chemotherapeutic waste” means waste that is contaminated through contact with, or having previously contained, chemotherapeutic agents, including, but not limited to, gloves, disposable gowns, towels, and intravenous solution bags and attached tubing that are empty. A biohazardous waste that meets the conditions of this paragraph is not subject to the hazardous waste requirements of Chapter 6.5 (commencing with Section 25100) of Division 20.

(6) “Trauma scene waste” means waste that is a regulated waste, as defined in Section 5193 of Title 8 of the California Code of

1 Regulations, and that has been removed, is to be removed, or is in
2 the process of being removed, from a trauma scene by a trauma
3 scene waste management practitioner.

4 *SEC. 2. This act is an urgency statute necessary for the*
5 *immediate preservation of the public peace, health, or safety within*
6 *the meaning of Article IV of the Constitution and shall go into*
7 *immediate effect. The facts constituting the necessity are:*

8 *In order to make statutory changes needed to exempt*
9 *over-the-counter human or veterinary drugs or dietary supplements*
10 *from laws regulating the management, handling, and disposal of*
11 *medical waste, as soon as possible, it is necessary that this act*
12 *take effect immediately.*